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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,205	10/29/2001	Richard Anthony Godwin Smith	62130-0002	2596

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,205	SMITH ET AL.	
	Examiner	Art Unit	
	AGNES B. ROOKE	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/11/2008 has been entered.

The amendments to the claims filed on 09/11/2008 have been acknowledged.

Status of Claims

Claims 9 and 19-21 are pending and under consideration. Claims 1-8, 10-18, and 22-24 are cancelled.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 19-21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite because it is unclear from the claim as presented where a particular basic amino acid sequence is present in the sequence in

relevance to the SEQ ID NO:1. Also, it is not clear whether the basic amino acid sequence is SEQ ID NO:1 or is the basic amino acid sequence embedded in SEQ ID NO:1? Examiner reviewed the sequence listing in regards to the basic amino acid sequence according to SEQ ID NO:1 and no explanation or any information regarding the basic amino acid sequence is mentioned in the description of the SEQ ID NO:1. Therefore, the claim is indefinite and unclear as written.

Claim 9 id indefinite because the language changes from a closed language: "a soluble derivative of a soluble polypeptide, wherein the soluble derivative **consist of**: " to an open language "wherein the soluble derivative **has** the amino acid sequence…" Therefore, proper correction is required.

Dependent claims 19-21 are included in this rejection since they do not cure the deficiencies of base claim 9.

Applicants responded that although the listing of SEQ ID NO:1 does not list detail of each of the parts of the construct, the description of the application itself makes it absolutely clear what is included in the construct, see PCT/GB00/00834, where the description discusses myristole group and electrostatic switch group in the construct in order to provide the membrane binding elements. Further, Applicants state that at the bottom of page 12 of the PCT, a description of the basic amino acid sequence is provided (amino acids 199 through 215 of SEQ ID NO:1). In addition, in the instant Remarks section, on page 5, Applicants discuss different fragment in relation to SEQ ID NO:1. In addition, Applicants refer to US 6,713,606 (columns 29 and 30, Example 8)

where one skilled in the art should be able to see what part of the sequence of SEQ ID NO:1 corresponds to SCR1-3 or the basic amino acid sequence.

Examiner responds that even through the clarifications presented by Applicants in regards to the different fragments of SEQ ID NO:1 are useful, as cited in the aforementioned PCT or US 6,713,606, claim 9 itself, is still indefinite, since one skilled in the art would be unable to ascertain which part of SEQ ID NO:1 is basic from claim 9 as presented. Examiner re-states that proper amendment would prevent this indefiniteness problem if the language as suggested by examiner was incorporated in to the claim: "wherein the soluble derivative consists of: a fragment of CR1 conjugated to myristoyl and a basic amino acid sequence of SEQ ID NO:1, wherein the CR1 fragment..." (see the detail rejection as presented above). Therefore, claim 9 is indefinite and the rejection is maintained.

The part of rejection in regards to SOLTRAN has been withdrawn since amendment to describe the "perfusion solution" was made in claim 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Smith et al**. (U.S. 6,713,606 B1) in view of the **Baxter**

SOLTRAN solution product #FKB4708G (see a copy of the Baxter product attached to this office action) and **Varty et al.,** "Response to organ shortage: kidney retrieval programme using non-heart beating donors," BMJ 1994, volume 308, page 575 (See Abstract as attached to this office action). The change in the rejection to Smith et al. in view of the Baxter SOLTRAN solution product and Varty et al is necessitated by Applicant's amendment.

Smith et al. teach CR1 fragments that would inherently include a fragment of CR1-3. Further, Claim 9 is included in this rejection because it refers to CR11 fragment and fragment of amino acids 2 through 215 will inherently be included in the structure of CR1.

Smith et al. teach soluble CR1 polypeptide that is derivatized with a myristoyl group (See column 17, line 55). At column 18, Smith et al. teach the use of peptides for Post-Ischemic Reperfusion Conditions. Thus, the reference clearly addresses the invention as recited in claim 9.

Smith et al. does not specifically teach SOLTRAN solution. However, according to Baxter Healthcare Ltd. SOLTRAN contains constituents (per 1 L of solution):. Potassium citrate 8.6g; Sodium citrate 8.2g; Mannitol 33.8g, for example. In addition, Applicants indicated in Remarks that such perfusion solution is commonly known and used in the prior art. Thus, SOLTRAN and the perfusion solution claimed by Applicants are equivalents.

As supporting evidence to the fact that SOLTRAN is a popular and widely used solution that is used as physiologically acceptable flush solution, examiner

included in the instant office action a copy of the Baxter's product that is sold as SOLTRAN solution and is commonly used in perfusion procedures.

Varty et al. teach that SOLTRAN produced by Baxter company was used in perfusion for organ donation purposes. (See third paragraph of the Abstract, on page 575 as included).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method for preparing an organ by perfusion prior to transplantation or storage of the organ that uses soluble CR1 polypeptide which includes a CR1-3 fragment that is derivatized with a myristoyl group and to administer such peptides to a patient or a transplant prior to implantation as taught by Smith et al. and to use in such a method the SOLTRAN product that is commonly used as a physiologically acceptable flush solution used in perfusion procedures as taught by Varty et al. One skilled in the art would be motivated to design such a method when SOLTRAN is utilized because such physiological solutions are commonly used in transplanting of different organs and preventing rejection of such organs. Therefore, the invention is *prima facie* obvious.

Applicants responded that in Figure 1 and the description, it is shown that the complement inhibitory effect is advantageously still seen for a period post-transplant, and that there is nothing in the cited references that would have suggested to one of ordinary skill, without hindsight, that a formulation according to the invention used in the method of the invention would provide a benefit of improved renal function post-translation during the first week of post-transplantation.

Examiner maintains the rejection because in column 19, lines 60-67, Smith et al. teach a method of delaying hyperacute allograft or hyperacute xenograft rejection in a human or non-human, which receives a transplant by administering an effective amount of a soluble complement inhibitor, such as soluble CR1 polypeptide and derivative, where such administration maybe to the patient or by application to the transplant prior to implantation. Also, one skilled in the art would assume benefits of such a method after transplantation. Therefore, Smith et al. teach administration of CR1 fragments or derivatives to patients before surgery or to the organs to be transplanted themselves (instant claims 19-21). Also, in regards to SOLTRAN, it is a physiologically acceptable flush solution that is routinely used during perfusion procedures and the name itself is trademarked.

Further, examiner would like to point out that the sequence of SCR1 is not specified in claim 9 and that the peptides of Smith et al. will inherently contain such a sequence that would have a function of complement inhibitory activity, and thus be effectively used in the method of preparing organ prior to transplantation or storage. Furthermore, the peptides or derivatives of Smith et al. are conjugated to myristoyl, as claimed in amended claim 9. Further, in view of the indefiniteness of the language in claim 9, the prior art still applies.

In addition, Applicants state that the paper by Varty et al. does not teach or suggest the combined use of SOLTRAN and a complement inhibitor construct nor the long term and lasting beneficial effect that is achieved.

Examiner responds that Varty et al. teach that SOLTRAN is used in perfusion for organ donation purposes and thus is commonly used as acceptable flush solution in transplanting of different organs and preventing rejection of such organism, and thus can be used in combination with other compounds, such as a soluble complement inhibitor, CR1 polypeptide or derivative, where such administration maybe to the patient or by application to transplant prior to implantation.

In addition, Applicants state that claim 16 was free of prior art rejection and has the sequence CR1 that consists of the first three Short Consensus Repeats (SCR1-3) and has a sequence according to positions 2 through 197 of SEQ ID NO:1, and that currently amended claim 9 also recites that the soluble derivative has the amino acid sequence of amino acids 2 through 215 of SEQ ID NO:1, and wherein the CR1 fragment has Short Consensus Repeats 1-3.

Examiner responds that claim 16 is cancelled and that the limitations of claim 16 were not incorporated in the instant claim 9, since claim 9 has different scope where compared with claim 16 as previously presented, because claim 16 provided the sequence for Short Consensus Repeats (SCR 1-3) as positions 2 through 197 of SEQ ID NO:1, and that the instant claim 9 does not incorporate such a sequence, for example. Therefore, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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/Karen Cochrane Carlson, Ph.D./

Primary Examiner, Art Unit 1656